questionnaires that were not based on patient interviews. The 25 and 18 item RMDQ is a measure of pain and function widely used in low back pain (LBP) trials that was based solely on clinician involvement. **METHODS:** Two US focus groups (n = 15) and one UK focus group (n = 7) were asked to complete the problem elicitation technique (PET) alongside the RMDQ to determine the relevance of items. The PET measures the importance of concepts based on a series of questions rating the importance of each item on a five-point likert response continuum. To ensure the RMDQ was not missing any relevant items participants were asked several open-ended questions. **RESULTS:** Participants confirmed the content validity of the RMDQ by identifying four areas of importance: pain/discomfort, activities of daily living, sleep problems and emotional impact. Based on the PET, all RMDQ items were rated as moderately to extremely important (item score range of 3.57–4.36 on a one—five scale). Items rated least important were the same items removed in the 18 item version. In the open ended questions, sleep disturbances was consistently mentioned as a primary area of concern. **CONCLUSIONS:** The PET augmented by open-ended questions is a valid method for confirming the content validity of questionnaires that did not include patient involvement in their development. These findings support the continued use of the RMDQ in LBP trials; however, consideration should be given to including additional sleep questions or measuring this concept separately.

Respiratory Diseases

RS1

QUALITY OF LIFE IN ASTHMA PATIENTS IS AFFECTED BY HOME TELEMANAGEMENT

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OBJECTIVES: To determine whether Home Automated Telemanagement (HAT) affects disease-specific Quality of Life (QOL) in adult asthma patients. **METHODS:** Fifty adult patients with mild persistent to severe asthma were randomly assigned to an intervention or control group and were followed for 12 months. The patients in the control group received regular care. The patients in the intervention group used HAT to monitor and manage their condition. The HAT system assisted clinicians in setting up individualized action plans and helped asthma patients in following their action plans at home using peak flow meter and a laptop connected with a hospital. **RESULTS:** Both intervention and control group patients had similar baseline demographic characteristics with regard to their asthma severity, action plan use, computer skills and the quality of life. After 12-month follow-up the mean total QOL score in the intervention and the control group was 20.2 ± 0.9 and 16.9 ± 1.3 respectively. The difference was significant ($p < 0.0001$) at the alpha level of 0.05. Analysis of the symptoms domain of the asthma quality of life showed improved score 5.3 ± 0.4 in the intervention group compared to the control group 4.4 ± 0.6 ($p < 0.05$). The activities domain of the QOL showed an improvement in the activities in the intervention group 5.1 ± 0.2 compared to the control group 3.7 ± 0.3 ($p < 0.05$). There was a statistically significant difference ($p < 0.05$) in the emotions domain of the QOL: the mean score in the intervention group was 4.8 ± 0.2 whereas the mean score in the control group was 4.4 ± 0.4. The environment domain in the intervention group was 5.1 ± 0.3 compared to 4.4 ± 0.5 in the control group ($p < 0.005$). **CONCLUSION:** Disease-specific quality of life in asthma patients is positively affected by Home Telemanagement.

RS2

ASSESSING HEALTH-RELATED QUALITY OF LIFE USING THE SF-12V2 FOR PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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OBJECTIVES: To assess health-related quality-of-life (HRQOL) for patients with chronic obstructive pulmonary disease (COPD). **METHODS:** In Spring 2004, 700 patients cared for by pulmonologists or general practitioners at 12 sites across the US completed a 90-item survey that included the SF-12v2 and pre-/post-bronchodilator spirometry. COPD was defined as post-bronchodilator Forced Expiratory Volume in one second/Forced Vital Capacity (FEV_1/FVC) <70%. Descriptive statistics for SF-12v2 measures were calculated for mild (FEV_1 >80% predicted) and moderate/severe (FEV_1 <80% predicted) COPD. Disease burden was estimated by adjusting general population normative data from the 1998 National Survey of Functional Health Status (NSFHS) to age and sex characteristics of the COPD sample. Multivariate and univariate analyses of variance (MANOVA, ANOVA) F-statistics were used to test for differences between patients' HRQOL and adjusted norms. **RESULTS:** Based on spirometry, 36% (N = 249) of patients had COPD (20% mild, 80% moderate/severe). Patients with COPD were less likely to describe their health as very good or excellent (20.5% vs. 36.8%, $p < 0.001$), and more likely to describe their health as fair or poor (33.3% vs. 23.4%, $p < 0.005$) compared to those without COPD. MANOVA revealed a significant difference between the full profile of SF-12v2 scales for COPD patients and the US general population ($p < 0.001$). Adjusted norm comparisons revealed that patients with mild COPD had significantly lower (mean, SD) Role Physical (41.9, 11.1; $p < 0.02$) and Physical Component Summary (PCS) (41.0, 12.0; $p < 0.02$) scores. Moderate/severe COPD patients had large, statistically significant decrements across all SF-12v2 measures. Differences from normative values were most notable for Physical Functioning (38.2, 12.8; $p < 0.001$), PCS (38.9, 11.7; $p < 0.001$), Role Physical (39.7, 11.9; $p < 0.001$), General Health (40.8, 11.2; $p < 0.001$), and Role Emotional (43.0, 13.0; $p < 0.001$). **CONCLUSION:** Compared to the US general population, COPD has a significant impact on a patient's HRQOL, notable with mild disease and pronounced at higher severity levels.

RS3

ESTIMATING THE COST-EFFECTIVENESS OF FLUTICASONE PROPIONATE FOR TREATING CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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OBJECTIVES: To explore the cost-effectiveness of fluticasone propionate (FP) for the treatment of chronic obstructive pulmonary disease (COPD), we estimated costs and quality adjusted life years (QALYs) over three-years, based on an economic appraisal of a previously reported clinical trial (ISOLDE). **METHODS:** Results from the initial analyses of the trial data showed significant improvements with FP in reducing the rate of exacerbations from COPD, in slowing the rate of decline in health status and a trend towards improved survival. A recently

published algorithm for the SF-36 generic instrument allowed the calculation of utility scores for quality of life suitable for calculating QALYs. Standard statistical techniques, including multiple imputation approaches to handle missing data, were employed to address missing data issues allowing the estimation of cumulative costs and QALYs over the three year study period. **RESULTS:** In the base case analysis we estimated the incremental costs of FP versus placebo to be GBP929 (95% confidence interval (CI): GBP633 to 1220) with an additional effect of 0.14 QALYs (CI: 0.07 to 0.20). This generates a cost-effectiveness estimate for the within-trial period of GBP6830 per QALY gained (CI: GBP3960 to 13,300/QALY gained) which includes uncertainty due to the imputation process. An alternative imputation approach did not materially affect this estimate. **CONCLUSIONS**: Previous analyses of the ISOLDE study showed significant improvement on disease specific health status measures and a trend towards a survival advantage for treatment with FP. This analysis shows that joint considerations of quality of life and survival result in a substantial increase in QALYs in favor of FP. Based on these data, FP appears cost-effective.

RS4

PRESCRIBING PATTERNS IN AMBULATORY CARE CENTERS FOR TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

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Chronic obstructive pulmonary disease (COPD) is primarily a disease of the elderly with increasing worldwide morbidity and mortality. Goals of treatment are to relieve symptoms, reduce airflow obstruction, and improve functioning. Although current treatment strategies and guidelines for long-term COPD management recognize bronchodilators as first-line therapy for all patients, inhaled corticosteroids are prescribed for some patients. **OBJECTIVE:** To characterize COPD medication prescribing patterns among visits of patients >=65 y across US ambulatory care centers. **METHODS:** Data from the 2002 National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey gathered from physician offices, hospital outpatient, and emergency departments were analyzed for patients >=65 y. COPD visits were identified by primary diagnoses of bronchitis, chronic bronchitis, emphysema, or chronic airway obstruction. Patients with coexisting asthma were excluded. Sample data were weighted to provide national estimates. **RESULTS:** In 2002, COPD accounted for 7.7 million ambulatory care visits among patients >=65 y. Of these visits, 54.6% were by females and 93.0% were by white patients. COPD medications were prescribed at 38.7% of visits with an average of 1.8 COPD medications prescribed per visit. Bronchodilators, alone or in combination, were prescribed at 2.0 million visits, representing 26.5% of visits. Prescribed bronchodilators were short-acting beta-agonists (16.4%), anticholinergics (11.8%), methylxanthines (7.5%) and long-acting beta-agonists (4.8%). Inhaled corticosteroids, alone or in combination, were prescribed at 13.4% of visits. The most commonly prescribed COPD medication combination was short-acting beta-agonists with anticholinergics (6.9%). **CONCLUSION:** Ambulatory care center prescribing patterns suggest that COPD medications may be under-prescribed in elderly patients. Bronchodilators appear to be the most common COPD-specific treatment. The frequency with which short-acting beta-agonists and anticholinergics were prescribed concurrently in this dataset may indicate a deficiency in acceptable therapies that provide sufficient bronchoconstriction relief. Further research is needed to assess optimization of drug management for elderly COPD patients.

Podium Session III

Cardiovascular I

CV1

DISCRETE EVENT SIMULATION TO ESTIMATE COST-BENEFIT OF PREVENTING SUDDEN CARDIAC DEATHS WITH AN IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) VS. AMIODARONE IN FRANCE

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OBJECTIVE: Until recently, primary prevention of sudden cardiac death depended on anti-arrhythmic drugs. The SCD-HeFT Trial confirmed the efficacy of ICD, as all-cause mortality was decreased 23% versus placebo. Estimating lives saved and economic impact of primary prevention of sudden cardiac death with an ICD versus amiodarone in France was the object of this study. **METHODS:** A discrete event simulation was developed to estimate effects over three years. Identical patients received either device or amiodarone. Post-implantation complications (lead and device-related) or toxicity from amiodarone could arise. Model parameters and risk functions were developed based on SCD-HeFT data, assuming life-threatening arrhythmia rates and other death are not differential. Probability of death given arrhythmia was 90% with amiodarone, 47% with ICD. To avoid ageism inherent in QALYs, the economic value society places on a life (5,697,127€) was derived from a meta-analysis and used in cost-benefit analyses. While estimates of the value of life vary from country to country, this value reflects a recent average for European countries. Costs are reported in 2004 € and discounted at 3%. In total, 100 replications of 1000 identical twin pairs were run. Sensitivity analyses were performed for key input parameters. **RESULTS:** ICD use in 1000 patients was predicted to prevent 62 premature deaths over three years. Total additional costs accrued were 20,121€ per patient. The cost/benefit ratio was 0.06 which means for every 1€ gained, 0.06€ has to be invested. In 55% of the replications ICD dominates Amiodarone. Investment in ICD is worthwhile whenever society values a life at more than 325,000€. **CONCLUSION:** ICDs increase immediate costs but their use is consistent with the value of life estimated in Western societies.

CV2

LIPID LEVELS AND NCEP ATP-III LDL-CHOLESTEROL GOAL ATTAINMENT IN PATIENTS NEWLY-INITIATED ON ROSUVASTATIN OR ATORVASTATIN

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OBJECTIVE: To compare effectiveness of rosuvastatin to atorvastatin on lipid levels (LDL-C, HDL-C, triglycerides, total cholesterol) and LDL-C goal attainment. **METHODS:** Patients newly-initiated on rosuvastatin or atorvastatin between August 1, 2003 and June 30, 2004 were identified from a West Coast health plan's claims data for this retrospective, longitudinal cohort study. Patients were excluded if they had any dyslipidemic therapy 12-months preceding their initial statin fill. Propensity score matching on baseline characteristics was used to minimize